

TO: FDA  
Dockets management Branch  
5630 Fishers Lane  
Room 1061 HFA-305  
Rockville, MD

Rec'd 6/22/01  
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FROM: Sherree L. Lewis  
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DATE: June 16, 2001

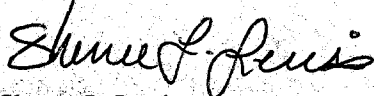
RE: Lotronex, Docket #01P-0169

I am a former Lotronex user. As you have heard from so many IBS sufferers, my quality of life for nearly 20 years was less than good. Until Lotronex became available, I was often confined to the house, afraid to go more than 10 mins. up the road. But I often tried to persevere, determined not to let my condition and the anxiety get the best of me. I went out anyway, often without eating and sick to my stomach, but I did it. I played softball, I went hiking, canoeing, and camping. But never on organized trips, and never with people who didn't know me well. Having to catch a flight and get to the airport early in the morning was hell. I could never sleep the night before, up hours early, in and out of the bathroom. Sometimes I had to miss events, and sometimes I turned down invitations. I missed some work time, and a few times I was late for appointments or meetings. More often than not, I was OK. But there were times when I wasn't. And I hate to admit to having a couple of very embarrassing episodes. I tried several meds. that helped some, but not always. I tried eliminating foods. I tried stress reduction techniques. I even tried seeing a naturopath. The ONLY thing that has ever truly worked for me was Lotronex. I did not suffer any side effects, but I did not start out with the full recommended dose. I am a member of an IBS online bulletin board, and I read accounts of those who were first trying the medication. Some complained of constipation, so I cut the dose in half. It was a godsend! In all of the 8 months I was on Lotronex, I can recall only 2 actual diarrhea episodes. For someone who suffered on the average once a week, this was truly a miracle! I was able to live a nearly normal life.

Please listen to the thousands of former and some still current Lotronex users to bring back this drug that is so desperately needed. There currently is no other treatment available for IBS that so successfully addresses its symptoms, nor is there any alternative drug in development. My physicians are of the opinion that most of those exhibiting severe problems either failed to heed warning signs or were too highly dosed.

There is a risk with ANY drug. If properly used and prescribed, as attested by the many successful users of Lotronex, the risk is minimal. Every voice is crucial, and time is of the essence.

Sincerely,



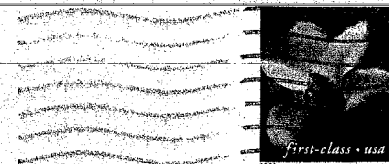
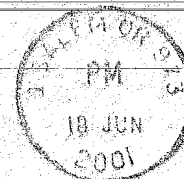
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Docket # OLP-0169

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